DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 2, 2014

LJT Surgical Ltd.
c/o Patsy J. Trisler, JD, RAC
Qserve Group US, Inc.
5600 Wisconsin Avenue, #509
Chevy Chase, MD 20815

Re: K140290
Trade/Device Name: StopLoss Jones Tube
Regulation Number: Preamendment
Regulation Name: Preamendment
Regulatory Class: Unclassified
Product Code: OKS
Dated: October 21, 2014
Received: October 24, 2014

Dear Ms. Trisler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K140290

Device Name: StopLoss Jones Tube System

Indications for Use:

The StopLoss Jones tube system is intended for use during repair of the lacrimal system for intubation and bypass to canalicular pathologies.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

510(k) SUMMARY

Submitter Name:	LJT Surgical, Ltd.
Submitter Address:	3-15 Wallace Way Hitchin, Hertfordshire SG4 0SE England
Contact Person:	Andrew Pearson Managing Director
Phone Number:	44 1628 782537
Date Prepared:	January 30, 2014; Revised October 6 2014
Device Trade Name:	StopLoss Jones Tube System
Device Classification:	Unclassified
Regulatory Name:	Lacrimal Stent and Intubation Set
Classification Number:	n/a
Product Code:	OKS
Predicate Device(s):	Gunther Weiss Scientific Glassblowing Co., Inc.: Jones Tube (Pre-Amendment device) DCS Surgical, Inc., DCS Lacrimal Stent (K113316)
Indications for Use Statement:	The StopLoss Jones tube system is intended for use during repair of the lacrimal system for intubation and bypass to canalicular pathologies.
Device Description:	The Stop*Loss* Jones Tube assembly consists of a flanged glass tube and silicone washer. The glass tube is Pyrex borosilicate glass and the silicone is NuSil. It is offered in a range of sizes as follows: ID 1.15 -1.25mm OD 1.90 - 2.10mm Lengths 9-22mm +/-0.5mm in 1mm increments The device is provided sterile for single use only.
Summary of Testing:	The following non-clinical bench tests were performed: The strength of the bond between the glass tube and the silicone washer using calibrated Instrom equipment was evaluated during stability testing. A pig nose model was used to establish the internal low profile for intubation of the lacrimal anatomy. Sterilization validation has been performed to assure the SAL of 10^{-6}, and packaging and shelf life testing allows for labeling the device with a 5-year shelf life.

The device was tested to assure maintenance of integrity after shipping (a transportation validation study).

The device was also tested to assure it is non-pyrogenic.

Biocompatibility of the materials and the final device have been presented in the 510(k).

Comparison to the Predicate Devices:

The StopLoss Jones Tube has the same intended use and the same principles of operation as both predicates. The materials used are the same as the borosilicate glass and silicone used to make the predicate devices.

The primary technological differences are that the StopLoss tube was designed with a silicone safety washer/flange which is not present on either predicate.

This difference does not introduce new types of questions of safety and effectiveness. The testing performed on the integrity of the flange and bond strength sufficiently addresses this difference.

Substantjal Equivalence Conclusion:

The comparisons and study data presented in the 510(k) lead to the conclusion that StopLoss Jones Tube is substantially equivalent to the predicate devices.